REMARKS

Claims 47-74 are pending in the subject application, with claims 47, 54, 56, 61, 68, and 70 being independent. Claims 1-46 have been cancelled without prejudice to or disclaimer of the subject matter contained therein, and new claims 47-74 have been presented herein. Support for the claim amendments is provided in the originally-filed application, and Applicant respectfully submits that no new matter is presented herein.

Initially, Applicant wishes to thank the Examiner for the courtesy extended during the personal interview conducted on August 22, 2007. This Amendment is being presented in an earnest attempt to place this application in condition for allowance. The Examiner is respectfully requested to contact the undersigned attorney, Dawn Russell, at 202-775-5771 if anything further is desirable in order to place this application in better condition for allowance.

Rejection under 35 U.S.C. § 112

Claim 42 was rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Without conceding the propriety of this rejection, Applicant submits that it is moot in view of the cancellation of claim 42, and respectfully requests withdrawal thereof.

The Claimed Invention

The presently-claimed invention relates to dosage forms for oral administration consisting of a ***compressed, homogenous mixture of a pharmacologically-active substance and a hydrostatic couple***, as well as dosage forms for oral administration including a ***capsule containing a homogeneous mixture of a plurality of compressed particles, each particle consisting of a mixture of a pharmacologically-active substance and a hydrostatic couple***.

The hydrostatic couple consists of a) at least one crosslinked hydrodynamic fluid-imbibing polymer selected from the group consisting of: i) an acrylic-acid polymer cross-linked with allylsucrose or allylpentaerythritol; ii) one or more starch derivatives cross-linked by epichlorhydrin, phosphorous oxychloride ($POCl_3$), or sodium trimetaphosphate; iii) a crosslinked polyglucan; iv) a crosslinked polyethylenimine; v) a crosslinked polyallylamine, and vi) combinations thereof; and b) at least one crosslinked

hydrostatic pressure-modulating agent selected from the group consisting of: i) a homopolymer of cross-linked N-vinyl-2-pyrollidone; ii) a rapidly expanding cross-linked cellulose derivative; and c) combinations thereof.

Support for the dosage forms of the presently-claimed invention may be found at least at page 11, lines 15-25 (pharmacologically-active substance); page 15, line 23, to page 16, line 2 (hydrostatic couple); page 17, lines 4-30 (crosslinked hydrodynamic fluid-imbibing polymer); page 18, lines 29-32, page 19, lines 13-23, and page 20, line 16, to page 21, line 10 (hydrostatic pressure modulating agent); page 23, lines 6-16 (dosage forms); page 23, lines 17-29 (excipients); page 28, lines 5-9 (coatings); as well as in the claims as originally-filed.

Applicant respectfully submits that none of the cited references (Dresdner, Jr. et al., Bai, Conte et al., and Rork et al.) disclose or suggest the claimed dosage forms for oral administration which include i) a compressed, homogeneous mixture of a pharmacologically-active substance and a hydrostatic couple, or ii) a capsule containing a homogeneous mixture of a plurality of compressed particles, where each particle consists of a mixture of a pharmacologically-active substance and a hydrostatic couple. The dosage forms for oral administration of the claimed invention beneficially provide controlled release of a pharmacologically-active substance contained within the delivery system, using non-osmotic hydrostatic differential pressure. *See* Applicant's specification, page 10, lines 12-14.

Rejections under 35 U.S.C. §§ 102(b)/103(a)

The outstanding Office Action rejected claims 1, 3-5, 7-8, 10, 12, 14, 21-23, 26-32, 34-35, 38-41, 43-44, and 46 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,357,636 (Dresdner, Jr. et al.), and claims 1, 5-6, 15-16, 19, and 42 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Dresdner, Jr. et al. Claims 14, 17-18, 20, 35, 37, 43, and 45-46 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,840,329 (Bai). Claims 1, 3-8, 10-12, 14-32, 34-35, 40-41, 43-44, and 46 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,582,838 (Rork et al.) and U.S. Patent No. 5,780,057 (Conte et al.).

Applicant respectfully traverses these rejections, and submits that they are moot in view of the fact that claims 1-46 have been cancelled herein.

With respect to newly-added claims 47-74, Applicant will now explain the substantial differences between the claimed invention and applied references.

Dresdner, Jr. et al.

Dresdner, Jr. et al. relates to a flexible glove including an antiseptic composition provided between inner and outer glove layers. The antiseptic substance may be provided in the form of a solid, powder, crystalline powder, etc. Any soft, deformable gas/liquid/solid combination formulations may be used. (Column 25.) The antiseptic composition may include one or more viscosity modifiers, such as a polymer or branched molecule of high molecular weight, which may include Carbopol, cellulose and suitable chemically-modified celluloses, and cross-linked PVP, etc., and mixtures thereof, which are useful to include when making gels, foams, pastes, puttys, greases, and the like. (Columns 35-36.) The antiseptic composition may also include antiseptics such as sodium perborate and sodium hypochlorite to increase viscosity. (Columns 34-35.)

The antiseptic compositions of Dresdner, Jr. et al. cannot be compressed without rendering the glove unsuitable for its intended use, *i.e.*, providing first order release of an antiseptic composition if the glove is punctured while it is being worn.

Accordingly, Applicant submits that the flexible glove of Dresdner, Jr. et al. does not disclose or suggest ***a dosage form for oral administration*** that includes a ***compressed, homogeneous mixture*** of a pharmacologically-active substance and a hydrostatic couple, or a ***capsule containing a homogeneous mixture of a plurality of compressed particles***, where each particle consists of a mixture of a pharmacologically-active substance and a hydrostatic couple. Claims 47-74 are therefore allowable over Dresdner, Jr. et al.

Bai

Bai relates to a pulsatile drug delivery system including a plurality of particles having multi-layer cores. The multi-layer cores may be formed from a controlled release matrix including a water-insoluble poly(acrylic acid) and a water-soluble polymer or

monomer, which may include a medicament. (Columns 5-6.) The water-soluble polymer or monomer of the controlled release matrix my include non-crosslinked PVP. (Column 7.) An external coating layer is required in Bai, which includes a major portion of water-insoluble, water-permeable polymer, a minor portion of water-insoluble, water swellable polymer, and a water-permeation adjusting agent. (Column 8.) A swelling layer may include crosslinked PVP or crosslinked cellulose as swelling agents. (Column 8.)

Accordingly, Applicant submits that the drug delivery system of Bai does not disclose or suggest a dosage form for oral administration that includes a ***compressed, homogeneous mixture*** of a pharmacologically-active substance and a hydrostatic couple, or a ***capsule containing a homogeneous mixture of a plurality of compressed particles***, where each particle consists of a mixture of a pharmacologically-active substance and a hydrostatic couple. Claims 47-74 are therefore allowable over Bai.

Rork et al. and Conte et al.

Rork et al. relates to a multi-layer tablet composition in which a single core comprises at least two layers, where one layer includes an active agent and a polymer that forms microscopic gel beads when hydrated, such as Carbopol, and a second layer includes a polymer that forms microscopic gel beads when hydrated. Other excipients may also be present in the layers of the core, including PVP and cellulose. (Column 8) An impermeable coating adheres to and surrounds the core, and contains apertures that provide an area for hydration and release of microscopic gel beads. The combination of the impermeable coating and the multiple layers having different compositions permit control over when the active agent is released.

Conte et al. relates to a multi-layer tablet composition including at least two layers. The dosage forms are designed to provide controlled release of active ingredients that are only absorbed in the stomach, duodenum, and the first portion of the small intestine. At least one layer contains a polymer that can rapidly swell on contact with fluids, thereby increasing the tablet volume, and increasing the residence time of the pharmaceutical in the stomach. Layer 26 may contain the active ingredient. (Column 4). Layer 26 may also include polymeric substances, such as acrylates, and

hydrophilic polymeric substances, such as cross-linked PVP and celluloses. (Columns 5-6) The swellable layer and an optional third layer may be impermeable to the active agent, and may form barriers that modulate the release of the active agent.

Accordingly, Applicant submits that the combination of the multi-layered tablets of Rork et al. and Conte et al. do not disclose or suggest a dosage form for oral administration that includes a ***compressed, homogeneous mixture*** of a pharmacologically-active substance and a hydrostatic couple, or a ***capsule containing a homogeneous mixture of a plurality of compressed particles***, where each particle consists of a mixture of a pharmacologically-active substance and a hydrostatic couple. Claims 47-74 are therefore allowable over Rork et al. and Conte et al.

The Presently Claimed Invention is Allowable Over the Cited References

In view of the above, Applicant respectfully submits that none of Dresdner, Jr. et al., Bai, Rork et al. and/or Conte et al., alone or in combination, discloses or suggests all features of the pending claims. As such, Applicant respectfully submits that the pending claims are allowable over the cited references.

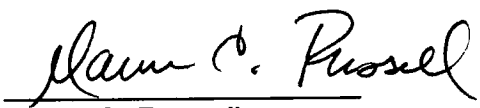
CONCLUSION

In view of the foregoing, reconsideration of the application, allowance of Claims 47-74, and the prompt issuance of a Notice of Allowability are respectfully solicited.

Should the Examiner believe anything further is desirable in order to place this application in better condition for allowance, the Examiner is requested to contact the undersigned at 202-775-5771.

In the event this paper is not considered to be timely filed, Applicant respectfully petitions for an appropriate extension of time. Any fees for such an extension, together with any additional fees that may be due with respect to this paper, may be charged to counsel's Deposit Account No. 01-2300, **referencing Attorney Dkt. No. 026806.00017**.

Respectfully submitted,



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